

REMARKS

Claims 1-21 are currently pending in this application. Claims 1, 6, 8, 11, 13, 17 and 20 have been amended. Applicants have carefully reviewed the Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Claim Objections

Claim 9 was objected to for reciting “the rest-indicating sensor” without antecedent basis. Claim 8 has been amended to recite “a sensor that indicates rest,” thereby providing antecedent basis for the rest-indicating sensor.

Claim Rejections Under 35 U.S.C. §103

Claims 1-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,385,144 (Yamanishi) in view of U.S. Patent No. 6,126,611 (Bourgeois).

Independent claims 1, 8, 13 and 17 relate to devices and methods that distinguish between central sleep apnea and obstructive sleep apnea based on oscillation of a parameter of cardiac electrical activity over a plurality of respiration cycles. For example, claim 1 recites, an implantable cardiac device comprising sensing circuitry to sense whether a patient is at rest, the sensing circuitry further being operative to sense cardiac electrical activity; and a sleep apnea detector to detect when a patient, who is at rest, is experiencing an episode of sleep apnea and to differentiate between central sleep apnea and obstructive sleep apnea based on oscillation of a parameter of the cardiac electrical activity, the cardiac electrical activity comprising evoked responses over a plurality of respiration cycles.

Yamanishi was cited as disclosing “a sleep apnea detector to detect when a patient is experiencing an episode of sleep apnea and to differentiate between central sleep apnea and obstructive sleep apnea based on a measure signal.” (Emphasis added.) Bourgeois was cited as disclosing the use of cardiac electrograms for detecting

rest or sleep apnea. The Office Action states that because Yamanishi and Bourgeois both disclose systems for diagnosing sleep apnea based on recorded physiological signal, it would have been obvious to modify Yamanishi's central-verses-obstructive sleep apnea diagnosis system with Bourgeois' cardiac electrogram in order to provide a further physiological parameter for diagnosis confirmation.

Regarding Yamanishi, the only "measured signal" disclosed and described therein is a base line of a pulse wave signal corresponding to arterial blood oxygen saturation as measured by an external pulse oximeter. Specifically, Yamanishi discloses a respiration diagnosis apparatus that detects the presence of sleep apnea based on the level of arterial blood oxygen saturation measured by an external pulse oximeter. See column 3, lines 38-46 and figure 4. Upon detection of sleep apnea, the amplitude and/or the rise/fall times of base line signal corresponding to arterial blood oxygen saturation signal are compared to respective thresholds to determine if the apnea is central or obstructive. See column 3, lines 46-58 and figure 4.

It is noted that Yamanishi does not teach or suggest distinguishing between central sleep apnea and obstructive sleep apnea based on oscillation of the amplitude of a particular portion of the base line signal, e.g., the peak amplitude of each waveform in figure 3(b). In fact, Applicants submit that because each of the base line signals disclosed in Yamanishi as being indicative of normal respiration (figure 3(a)) and obstructive sleep apnea (figure 3(b)) have constant peak amplitudes, Yamanishi inherently teaches that oscillation of the amplitude of a particular portion of a "measured signal" cannot be used as a means for either identifying or distinguishing between central and obstructive sleep apnea.

Regarding Bourgeois, it discloses a sleep apnea management device that includes means for detecting an apnea event and means responsive to the detection of apnea for stimulating the heart at a rate higher than its natural rate. See abstract. Means for detecting an apnea event, as disclosed in Bourgeois, consist of cardiac electrogram analysis to detect a low heart rate below a threshold (column 3, lines 14-17 and column 4, lines 4-5); minute ventilation or respiration rate or pressure or impedance

sensing (column 3, lines 26-29 and column 5, lines 35-41); monitoring inspiratory effort or respiratory functioning (column 5, lines 23-25); and monitoring electrical activity associated with contraction of the diaphragm and also pressure within the thorax and the upper airway (column 5, lines 26-30).

It is significant to note that Bourgeois is not concerned with – and does not teach or suggest any method of, or means for – distinguishing between central sleep apnea and obstructive sleep apnea. Further, regarding its teaching with respect to cardiac electrograms, it is significant to note that the cardiac electrogram analysis in Bourgeois is used only in a conventional heart-rate-detection manner as a means to detect rest or sleep apnea. Bourgeois simply does not teach or suggest any means of distinguishing between obstructive sleep apnea and central sleep apnea, and in particular the use of the cardiac electrogram and oscillation of the amplitude of a particular portion of the cardiac electrogram as such a means.


In view of the foregoing, Applicants submit that neither Yamanishi nor Bourgeois, either alone or in combination, teach or suggest the combination of elements and features recited in independent claims 1, 8, 13 and 17, including in particular the use of oscillation of a parameter of cardiac electrical activity or an IEGM signal over a plurality of respiration cycles to differentiate between central sleep apnea and obstructive sleep apnea. Accordingly, Applicant requests reconsideration of the §103 rejections of claims 1, 8, 13 and 17 and their respective dependent claims.

CONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicants' claims 1-21 is believed to be in order.

Respectfully submitted,

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Date



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